REMARKS

Claims 1, 3-14, 32 and 38-55 were examined. Claims 1, 7, 38, 48-49 and 53 are amended. Claims 1, 3-14, 32 and 38-55 remain in the Application.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the above-referenced claim objections to claims 48 and 53.

I. Claim Rejections – 35 U.S.C. §102

In the outstanding Action, claims 1, 3, 5-9, 12, 14, and 48 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,602,241 issued to Makower, et al. ("Makower").

It is axiomatic to a finding of anticipation that each and every element of the rejected claim be found within a single prior art reference.

Independent claim 1 recites:

> 1. A method comprising:
> positioning a distal portion of a delivery device at a location in a blood vessel the distal portion of the delivery device comprising a delivery lumen;
> imaging a thickness of at least a portion of a wall of the blood vessel at the location with an imaging assembly disposed in a lumen of the delivery device;
> identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging;
> advancing a needle beyond the lumen of the delivery device a distance into the wall of the blood vessel to the treatment site beyond the external elastic lamina of the blood vessel; and
> after advancing the needle, introducing a treatment agent in a sustained release composition through the needle.

In regard to independent claim 1, Applicants respectfully submit that Makower fails to teach at least the elements of "identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging" and "advancing a needle beyond the lumen of the delivery device a distance into the wall of the blood vessel … and … introducing a treatment agent thought the needle" as recited in amended claim 1.

The Patent Office alleges that Makower discloses a method of delivering substances to extravascular treatment sites including advancing a catheter into a blood vessel and imaging 360 degrees about the vessel wall to locate a treatment site. The Patent Office alleges that Makower further discloses that after imaging, the catheter is advanced through the vessel wall to deliver a treatment agent to the target site, including a sustained release treatment agent and/or inflammation inducing agent. Apparently recognizing the failure of Makower to disclose imaging a thickness of the vessel wall, the Patent Office alleges that this feature would be inherently provided by the imaging step disclosed in Makower. See Action, page 2.

As acknowledged by the Patent Office, Makower does not describe imaging of a thickness of the vessel wall. Rather, Makower discloses the use of a guidance element for "the positioning and rotational orientation of the catheter 11 within the vasculature such that the vessel wall penetrator 85 will be properly aimed in the direction of the target site." See Makower, col. 8, lines 20-25. Makower further discloses that the guidance element may include an imaging transducer that "emits ultrasound signals and receives back echos or reflections which are representative of the nature of the surrounding environment." See Makower, col. 8, lines 40-45. Thus, Makower clearly discloses that the information obtained from the guidance element relates to the structure of the vessel wall surrounding the catheter, not the structure beyond the vessel wall, so that the penetrator 85 can be aimed at the desired wall region. Imaging of a thickness of the vessel wall is neither relevant nor considered by Makower to properly direct penetrator 85. Accordingly, any inherent imaging of the thickness of the vessel wall that may occur using the guidance element of Makower is not used to identify a treatment site beyond an external elastic lamina of the blood vessel as required by amended claim 1.

Further, Makower discloses penetrating catheter 11 having penetrator 85 that penetrates tissue. Delivery catheter 12 is then advanced through a lumen of penetrator 85. In contrast, claim 1 describes that the needle advances beyond a delivery lumen into a wall of a blood vessel and a treatment agent is introduced through the needle. The needle is penetrating as opposed to penetrator 85 in Makower.

Since Makower fails to teach each and every element of independent claim 1, claim 1 is not anticipated by the cited prior art reference. Applicants respectfully requests reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §102 over Makower.

In regard to claims 3, 5-9, 12, 14 and 48, these claims depend from claim 1 and therefore incorporate the limitations thereof. Thus, for at least the reasons that claim 1 is not anticipated by Makower, claims 3, 5-9, 12, 14 and 48 are further not anticipated by the cited prior art reference. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 3, 5-9, 12, 14 and 48 under 35 U.S.C. §102 over Makower.

II. Claims Rejections – 35 U.S.C. § 103

A. In the Action, claims 4 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of U.S. Patent No. 6,514,217 issued to Selmon, et al. ("Selmon").

To establish a *prima facie* case of obviousness, the Examiner must set forth "some articulated reasoning with some rational underpinning to support the conclusion of obviousness." See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). In combining prior art elements to render the claimed combination of elements obvious, the Examiner must show that the results would have been predictable to one of ordinary skill in the art. See *Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103*, Section III(D), issued by the U.S. Patent and Trademark Office on October 10, 2007.

In regard to claims 4 and 32, these claims depend from claim 1 and incorporate the limitations thereof. As noted above, Makower does not disclose the limitations of "identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging" and "advancing a needle beyond the lumen of the delivery device a distance into the wall of the blood vessel … and … introducing a treatment agent through the needle" as incorporated into claims 4 and 32 from claim 1. Selmon further fails to cure the deficiencies of Makower with respect to these elements. Thus, for at least the foregoing reasons, claims 4 and 32 are not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 4 and 32 under 35 U.S.C. §103 over Makower and Selmon.

B. In the Action, claims 7-8, 10-13 and 46-47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower.

In regard to claims 7-8, 10-13 and 46-47, these claims depend from claim 1 and incorporate the limitations thereof. As noted above, Makower does not disclose the limitations of "identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging" and "advancing a needle beyond the lumen of the delivery device a distance into the wall of the blood vessel ... and ... introducing a treatment agent through the needle" as incorporated into claims 7-8, 10-13 and 46-47 from claim 1. Thus, for at least the reasons previously discussed, claims 7-8, 10-13 and 46-47 are further not obvious over the cited prior art reference. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 7-8, 10-13 and 46-47 under 35 U.S.C. §103 over Makower.

C. In the Action, claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of U.S. Patent Publication No. 2002/0131974 of Segal ("Segal").

In regard to claim 11, this claim depends from claim 1 and incorporates the limitations thereof. For at least the reasons previously discussed, Makower does not disclose the limitations of "identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging" and "advancing a needle beyond the lumen of the delivery device a distance into the wall of the blood vessel ... and ... introducing a treatment agent through the needle" as incorporated into claim 11 from claim 1. Segal does not cure these deficiencies of Makower with respect to these elements. Thus, for at least the foregoing reasons, claim 11 is not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 under 35 U.S.C. §103 over Makower and Segal.

D. In the Action, claims 12-13 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of U.S. Patent No. 5,749,915 issued to Slepian ("Slepian").

In regard to claims 12-13 and 47, these claims depend from claim 1 and incorporate the limitations thereof. As noted above, Makower does not disclose the limitations of "identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging" and "advancing a needle beyond the lumen of the delivery device a distance into the wall of the

blood vessel ... and ... introducing a treatment agent through the needle" as incorporated into claims 12-13 and 47 from claim 1. Slepian does not cure the deficiencies of Makower with respect to these elements. Thus, for at least the foregoing reasons, claims 12-13 and 47 are not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 12-13 and 47 under 35 U.S.C. §103 over Makower and Slepian.

E. In the Action, claims 44-45 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Makower in view of U.S. Patent No. 5,676,151 issued to Yock ("Yock") or U.S. Patent No. 6,338,717 issued to Ouchi ("Ouchi").

In regard to claims 44-45, these claims depend from claim 1 and incorporate the limitations thereof. As noted above, Makower does not disclose the limitations of "identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging" and "advancing a needle beyond the lumen of the delivery device a distance into the wall of the blood vessel ... and ... introducing a treatment agent through the needle" as incorporated into claims 44-45 from claim 1. Neither Yock nor Ouchi cure the deficiencies of Makower with respect to these elements. Thus, for at least the foregoing reasons, claims 44-45 are further not obvious over the cited prior art references. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 44-45 under 35 U.S.C. §103 over Makower and Yock or Ouchi.

F. Claim 55 is rejected under 35 U.S.C. §103(a) as obvious over Makower in view of U.S. Patent No. 5,725,551 of Myers et al. (Myers). Myers describes an apparatus and method for sealing an arteriotomy site. Myers describes that wall thickness of a vessel can be determined using methods such as ultrasound or other imaging techniques.

Claim 55 depends from claim 1 and incorporates the limitations therefore. Thus, for at least the reasons that claim 1 is not anticipated by, or prima facie obvious in view of, the cited prior art references, claim 55 is further patentable over the art of record. Claim 55 is further patentable for at least the reasons that the prior art of record fails to disclose the additional elements of "measuring the thickness of the portion of the wall of the blood vessel using the imaging assembly; and identifying the treatment site based on the imaging and measuring" as

recited in claim 55. Myers is determining a thickness of a vessel so that it can seal an opening. As noted above, a thickness of a vessel wall is of no relevance to Makower. Therefore, there is no prediction of success to incorporate a determination of a vessel wall thickness in Myers to the technique of Makower.

G. Claims 38-43 and 51-53 are rejected under 35 U.S.C. §103(a) as obvious over Makower in view of U.S. Patent No. 6,190,353 of Makower (Makower II). Makower is cited for the teaching mentioned above. Makower II is cited for the use of a balloon.

With reference to Makower II, a balloon is used to block a blood vessel lumen (see col. 23, lines 17-19) or to deter or prevent a tissue penetrating element from recoiling and pressing a contralateral wall of a blood vessel and to stabilize and hold a distal portion of the catheter device (see col. 33, lines 19-33). Makower II does not describe the use of a balloon to direct a portion of a delivery device toward a wall of a blood vessel.

Independent claim 38 recites:

> 38. A method comprising:
> positioning a distal portion of a delivery device at a location in a blood vessel;
> imaging a thickness of at least a portion of a wall of the blood vessel at the location with an imaging assembly disposed in a lumen of the delivery device;
> directing the distal portion of the delivery device toward the portion of the wall of the blood vessel by inflating a balloon disposed around the lumen of the delivery device;
> advancing a needle beyond the distal portion of the delivery device a distance into the wall of the blood vessel to a treatment site beyond an external elastic lamina of the blood vessel; and
> after advancing the needle, introducing a treatment agent through the needle,
> wherein the treatment agent comprises an inflammation-inducing agent.

In regard to independent claim 38, Applicants respectfully submit that Makower and Makower II fail to teach at least the elements of "directing the distal portion of the delivery device toward the portion of the wall of the blood vessel by inflating a balloon disposed around the lumen of the delivery device" and "advancing a needle beyond the distal portion of the delivery device a distance into the wall of the blood vessel … and … introducing a treatment

agent through the needle," as recited in amended claim 38. Makower discloses a vessel wall penetrating catheter 11 including a vessel wall penetrator 85 and delivery catheter 12 that may be advanced out of the vessel wall penetrator 85 into the tissue. The vessel wall penetrating catheter 11 of Makower does not include a balloon, much less a balloon for directing the distal portion of the delivery device toward the portion of the vessel wall by inflating the balloon as required by claim 38. Makower II does describe embodiments including a balloon but not to direct a portion of a delivery device toward a wall of a blood vessel.

Further, Makower fails to disclose advancing a needle beyond a distal portion of a delivery device a distance into a wall of a blood vessel. Makower uses penetrator 85 to penetrate tissue and to provide a lumen for delivery catheter 12.

For at least the foregoing reasons, claim 38 is not obvious over the combined teachings of Makower and Makower II. Claims 39-43 and 51-53 depend from claim 38 and therefore contain all the limitations of that claim and for at least the noted reasons, are not obvious over the cited references. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

H. Claims 41-43 and 52 are rejected under 35 U.S.C. §103(a) as obvious over Makower in view of Makower II and Slepian. Claims 41-43 and 52 depend from claim 38 and therefore contain all the limitations of that claim. For at least the reasons noted above with respect to claim 38, claims 41-43 and 52 are not obvious over the cited references. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

I. Claims 49-50 are rejected under 35 U.S.C. §103(a) as obvious over Makower in view of Makower II or Yoek or Ouchi. Claims 49-50 depend from claim 38 and therefore contain all the limitations of that claim. For at least the reasons noted above with respect to claim 38, claims 49-50 are not obvious over the cited references. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

J. Claim 54 is rejected under 35 U.S.C. §103(a) as obvious over Makower in view of Makower II and Selmon. Claim 54 depends from claim 38 and therefore contains all the limitations of that claim. For at least the reasons noted above with respect to claim 38, claim 54 not obvious over the cited references. Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

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